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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,251	02/24/2004	Stanley W. Olson JR.	02-125 (US02)	2722

41696 7590 06/27/2008
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EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT	PAPER NUMBER
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3733

MAIL DATE	DELIVERY MODE
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06/27/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/786,251	Applicant(s) OLSON ET AL.	
	Examiner JERRY CUMBERLEDGE	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-60 and 64-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-60 and 64-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 48-55 and 66-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 48 recites "...the pliable sealing member having, in an uncompressed state, a diameter that is larger than the diameter the lumen of the cannula body..."

Initially, it appears that "of" should be inserted between "diameter" and "the".

Secondly, there is insufficient antecedent basis for this limitation (*i.e.* "...the lumen of the cannula body...").

Claim 66 recites "the pliable sealing member has a diameter that is larger than the diameter the lumen of the cannula body". Initially, it appears that "of" should be inserted between "diameter" and "the". Secondly, there is insufficient antecedent basis for this limitation (*i.e.* "...the lumen of the cannula body...").

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application

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by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 56-58, 60, 64 and 65 are rejected under 35 U.S.C. 102(e) as being anticipated by Margulies et al. (US Pat. 6,679,890 B2).

Margulies et al. disclose a method for delivering implant material into body tissue using a cannula, the cannula comprising a cannula body having a proximal end (Fig. 1), a distal end (Fig. 1), and one or more openings (Fig. 1, refs. 15 and 11), the method comprising: inserting the cannula body into body tissue (Fig. 1), the cannula body including a plurality of notches (Fig. 3a) disposed in the wall of the cannula body (Fig. 3a); perfusing the implant material out of the one or more openings into the tissue (column 5, lines 40-61); and separating the proximal end from the distal end of the cannula body at one of the plurality of notches (column 5, lines 64-67). The one or more openings comprises a plurality of openings axially spaced from each other along the cannula body the method further comprising perfusing the implant material out of the plurality of openings into the tissue (column 5, lines 40-61). The method further comprises implanting the distal end of the cannula body within the tissue (Fig. 1). The distal end of the cannula body is composed of a biocompatible material (column 6, lines 37-47).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over
Margulies et al. (US Pat. 6,679,890 B2) in view of Reiley et al. (US Pat. 6,248,110 B1).

Margulies et al. disclose the claimed method except for the bone tissue being a vertebral body.

Reiley et al. disclose a method for delivering implant material into tissue using a cannula (column 1, lines 53-65), where the tissue can be either a vertebral body (Fig. 39D) or other bones of the body (column 6, lines 3-8) and the method is used to treat fractures or other conditions of bone systems (column 1, lines 35-38).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have used the method of delivering implant material into tissue using a cannula of Margulies et al. in the vertebra as taught by Reiley et al., in order to treat fractures or other conditions of bone systems (column 1, lines 35-38).

Response to Arguments

Applicant's arguments filed 03/19/2008 directed to claim 56 have been fully considered but they are not persuasive.

With regard to Applicant's argument that the proximal end of the cannula body is not separated at one of the plurality of notches, the examiner respectfully disagrees. The cannula has a plurality of notches along the longitudinal axis (Fig. 3a, e.g. ref. 58, ref. 60). When the cannula is trimmed (column 5, lines 64-67) the cannula will be cut at

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at least one of the notches (*i.e.* between threads or between enlarged portions of the longitudinal shaft).

Allowable Subject Matter

Claims 48-55 and 66-68 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY CUMBERLEDGE whose telephone number is

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(571)272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. C./

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733